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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Anthony John Ujhazy

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EXAMINER

BEHRINGER, LUTHER G

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/598,136	Applicant(s) UJHAZY ET AL.	
	Examiner LUTHER G. BEHRINGER	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-15,32,33 and 35-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-15,32,33 and 35-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 June 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This office action is in response to the communication received on 04/14/2009 concerning application no. 10/598136 filed on 08/18/2006.

Response to Arguments

2. Applicant's arguments with respect to claim(s) 1, 3 – 15, 32 and 33 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claim(s) 1, 3, 4, 13, 14 and 35 – 37 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over **Stahmann et al. (US 2005/0043644, herein Stahmann)**.

With regard to **claim(s) 1 and 35 – 37**, Stahmann discloses a method of treating sleep disordered breathing comprising the steps of: implanting a device in a patient (Abstract), determining the likelihood of said patient being asleep [0044], delivering treatment so as to prevent airway collapse if said patient is likely to be asleep [0031, 0044], determining the presence of an obstruction in said patient's airway, and if an obstruction is present increasing said treatment until said obstruction is no longer present [0031], wherein said device includes a stimulator for providing electrical stimulation to afferent nerves, *hypoglossal nerve stimulation* [0031], a postural sensor to

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sense said patient's postural state [0049], inherently a real time clock, and a detector to detect transthoracic impedance changes by 1) emitting high frequency electrical pulses to traverse the transthoracic cavity, 2) calculating an instantaneous transthoracic impedance signal across said transthoracic cavity, and 3) comparing said instantaneous signal to a recent average of instantaneous transthoracic impedance signals [0095], said treatment comprises operating said stimulator to apply electrical stimulation to afferent nerves [0031], said presence of an obstruction is determined by detecting a change in transthoracic impedance [0095] and the likelihood of said patient being asleep is inherently determined based upon the time of day as identified by said real time clock together with the patient's postural state as sensed by said postural sensor [0049, 0051].

While Stahmann is not explicit concerning a real time clock registering the time of day, numerous references are made to registering time periods, specifically nocturnal time periods and historical sleep times [0045, 0048 & 0064] all of which would require a real time clock to accurately record apneic events.

5. Further, while Stahmann does not explicitly disclose "high frequency" electrical pulses to determine transthoracic impedance, one of ordinary skill in the art at the time of the invention would have found it obvious to utilize a frequency higher than respiration and cardiac activity to allow the filtration and removal of these artifacts from the signal of interest, increasing the reliability of the transthoracic impedance calculation.

Regarding **claim 3**, Stahmann discloses wherein the site of electrical stimulation is within or adjacent to the genioglossus muscle, *electrical activation of the tongue muscles* [0031].

With regard to **claim 4**, Stahmann discloses wherein the site of electrical stimulation is in the vicinity of the hypoglossal motor nucleus or excitatory afferent nerve pathways leading to this structure [0031].

Regarding **claim 13**, Stahmann discloses wherein stimulation is repeated in accordance with the detected state of the airway [0054].

With regard to **claim 14**, Stahmann discloses wherein stimulation is carried out in accordance with a model of Cheyne-Stokes Respiration [0055].

6. Claim(s) 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Stahmann et al. (US 2005/0043644, herein Stahmann)** in view of **Testermann et al. (US 5,540,733, herein Testermann)**.

Regarding **claim 5**, Stahmann fails to disclose wherein the electrical stimulation comprises trains of electrical pulses.

However, Testermann teaches wherein the electrical stimulation comprises trains of electrical pulses (Figs. 10 – 17; Col. 8, l. 54 – Col. 9, l. 30).

7. A person of ordinary skill in the art, upon reading the reference, would have recognized the desirability of providing trains of electrical pulses to achieve reliable, consistent stimulation that extends battery life. Thus, it would have been obvious to a

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person having ordinary skill in the art at the time of the invention to modify Stahmann to include electrical pulse train stimulation as taught by Testermann, since it is well known in the art that pulse train stimulation is an effective means of stimulation that extends battery life in medical implants.

With regard to **claim 6**, Stahmann in view of Testermann fails to disclose wherein the train length is approximately 10-30 pulses.

8. Stahmann in view of Testermann discloses the claimed invention except for the specified length of the pulse train. It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize a pulse train length of 10 – 30 pulses, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

9. Claim(s) 7, 8, 15, 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Stahmann et al. (US 2005/0043644, herein Stahmann)** in view of **Bowers (US 5,207,230)**.

Regarding **claim(s) 7 and 15**, Stahmann discloses all of the limitation of claims 7 and 15 as disclosed in claim 1 above, with the exception of utilizing mechanical stimulation to accomplish stimulation of afferent nerves.

However, Bowers teaches a method of treating sleep disordered breathing comprising the step of mechanical stimulation of nerves to increase muscle tone of upper airway muscles (Col. 3, ll. 20 – 23).

10. It would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the disclosure of Stahmann with the teachings of Bowers to provide an alternative mechanical stimulation of nerves that more efficiently delivers apneic therapy.

With regard to **claim 8**, Stahmann in view of Bowers discloses wherein mechanical stimulation is performed by a piezo-electric mechanical element (Bowers: Col. 3, ll. 20 – 23) implanted at a site in the vicinity of the patient's upper airway (Stahmann: [0031]).

With regard to **claim 32**, Stahman in view of Bowers discloses wherein stimulation is repeated in accordance with a detected change in transthoracic impedance (Stahmann: [0054]).

Regarding **claim 33**, Stahmann in view of Bowers discloses wherein stimulation is carried out in accordance with a model of Cheyne-Stokes Respiration (Stahmann: [0055]).

11. Claim(s) 9 – 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Stahmann et al. (US 2005/0043644, herein Stahmann)** in view of **Bowers (US 5,207,230)** in view of **Pitts (US 2002/0049479)**.

Regarding **claim 9**, Stahmann in view of Bowers fails to disclose wherein the piezo-electric mechanical element is implanted within or adjacent to the base of the genioglossus muscle.

However, Pitts discloses wherein the piezo-electric mechanical element is implanted within or adjacent to the base of the genioglossus muscle (Pitts: Abstract).

12. A person of ordinary skill in the art, upon reading the reference, would have recognized the desirability of implanting the piezo-electric mechanical element within or adjacent the desired stimulation location to achieve adequate therapy delivery to the desired tissue. Thus, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify Stahmann in view of Bowers to include implanting the piezo-electric mechanical element within or adjacent the desired stimulation location as taught by Pitts, since appropriate placement of a stimulation device leads to optimum stimulation of the desired tissue.

With regard to **claim(s) 10 and 11**, Stahmann in view of Bowers in view of Pitts discloses wherein the mechanical stimulation is duration of the stimulation is on the order of several seconds of vibration (Bowers: Col. 10, ll. 25 – 30; Pitts: [0029]).

Regarding **claim 12**, Stahmann in view of Bowers in view of Pitts discloses wherein the mechanical vibration occurs at frequencies in the range of 10-50 Hz (Pitts: [0029]).

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LUTHER G. BEHRINGER whose telephone number is (571)270-3868. The examiner can normally be reached on Mon - Thurs 9:00 - 6:30; 2nd Friday 9:00 - 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carl H. Layno/
Supervisory Patent Examiner, Art Unit 3766

/Luther G Behringer/
Examiner, Art Unit 3766